DOCUMENT RESUME

ED 144 428 HE 009 200

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TITLE Current Trends in Government Patent Policy.
PUB DATE Jun 77
NOTE 15p.; Paper presented at the Conference on University Research Management (New York Univ., New York, June 6, 1977)

EDRS PRICE MF-$0.83 HC-$1.67 Plus Postage.
DESCRIPTORS Federal Government; *Federal Legislation; *Government Role; *Higher Education; Industrial Technology; Industry; *Patents; Research; *Research Utilization; Technological Advancement; Technology; Universities

ABSTRACT

Government funded research is approaching 60 percent of the total research conducted in this country and is still growing as a percentage of the total. The government patent policy during the 1960s and 1970s is briefly outlined and shown as permitting the agencies to use their discretion to determine whether or not the normal incentives of the patent system should be applied. This cannot help but to undermine the integrity of our patent system if essentially all decisions result in Government ownership without further effort toward commercialization. Two alternate patent policies have been proposed and are discussed. The proposal favored at this time would establish a uniform Federal policy providing contractor retention of ownership of inventions resulting from Federally-sponsored research if they have sufficient interest to seek patent protection and declare an intent to commercialize the invention, subject to strong "march-in" rights in the Government. (JMF)

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ED144428

CURRENT TRENDS IN GOVERNMENT PATENT POLICY

June 6, 1977

Presentation By

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Before

Conference on University Research Management

New York University

Of course, these are my own views and are not necessarily consistent with those of my Department or the Administration.

In 1971 the controversy regarding the appropriate policy for disposing of inventions resulting from Government funded research surfaced again as a public issue after being relatively dormant since the 1965 attempts by Senator Long to amend the NASA and Public Health Service appropriation bills to assure ownership of such inventions in the Government. As I will explain later, there are now serious attempts in both the Legislature and the Executive toward bringing the controversy to some conclusion. In order for you to follow the public debate that may be precipitated by recommendations already made or to be made, I thought it might be useful to comment on the more significant events leading to the present state of the policy debate.

HE009200

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The first apparent catalyst of the more recent discussions appears to have been the reissued President's Statement of Patent Policy of 1971. The '71 Statement differed from the previous '63 Statement by providing to the Executive agencies, not otherwise precluded by Statute, greater flexibility in (1) permitting Government contractors to retain exclusive rights in their inventions after they have been identified, and (2) granting exclusive rights in inventions owned by the Government to licensees other than the inventing organization. These changes were made to correct identified problems in agencies such as HEW in bringing the results of their research to the marketplace. The '71 Statement made no changes in the criteria governing disposition of invention rights at the time of contracting.

To implement the new exclusive licensing authority, the '71 Statement required Government-wide licensing regulations. Soon after the issuance of these regulations, Public Citizens, Inc., a Ralph Nader organization, joined by eleven Congressmen, sued the Government to enjoin their implementation on the primary basis that any grant of an exclusive license under the regulations without statutory authority was an unconstitutional disposition of property.

Shortly after the issuance of the '71 Statement, the Commission on Government Procurement, formed by a charge from Congress, began review of Government patent policy. The Commission's December 1972 report contained 16 recommendations on Intellectual Property Matters. The first and second recommendations suggest:

1) Implementation of the '71 Statement promptly and uniformly, and

2) Enactment of legislation to make clear the authority of all agencies to issue exclusive licenses under agency-owned patents.

The first recommendation did not in fact follow the recommendation of the Commission's "Task Force on Disposition of Invention Rights." That Task Force, made up of representatives from the private and public sectors, indicated in its report to the Commission a dissatisfactqon with the '63 and '71 State ments. The Task Force indicated that the Executive agencies were not uniformly utilizing the discretion provided to them by the Statements in recognizing the equities of contractors in resulting inventions in appropriate cases. The Task Force felt the lack of uniform treatment was adversely affecting contractor participation in Government research programs and ultimate delivery of the inventive results of these programs

to the public. The Task Force recommended ending the discretion left to the agencies by requiring use of a single invention rights clause in all research and development contracts providing ownership in all resulting inventions in the contractor subject to strengthened march-in provisions in the Government.

One basis for the recommendation was the realization that a substantial majority of inventive ideas require "advocates" in order to reach the marketplace, and that the inventing organization, if interested, is a more likely "advocate" than a less proximate Government staff.

History is replete with examples of inventions now commonly accepted which reached fruition only due to the perseverance of an advocate. It is said that the inventor of Xerox, Chester Carlson, contacted over 100 concerns before he was able to obtain a financial commitment for development. Similarly, Samuel B. Morse argued through 5 years before he was able to obtain $30,000 from Congress to build a test line for his telegraph between Washington and Baltimore. There is little evidence that a Government organization would be willing to duplicate that kind of effort, nor is it apparent that many organizations or persons would, absent a property right.

Other factors supporting the Task Force recommendations were the recognition that the contractor had an equitable position in future invention rights on the mere basis that its selection as a contractor was indicative of its prior background position.

Further, in the case of the University contractor, the ownership of its ideas is deemed imperative to the University's continued involvement in obtaining industry collaboration in delivery to the market. This is based on the belief that inherent to the transfer of the innovative results of the research conducted in University laboratories to industrial developers is a decision on the part of the developer that the intellectual property rights in the innovation being offered for development are sufficient to protect its risk investment. Of course, not all transfers of potentially marketable innovations from such laboratories require an exchange of intellectual property rights in the innovation, but it is unpredictable in which transfers the entrepreneur will demand an exchange to guarantee its collaborative aid. Notwithstanding, where substantial risk investment is involved, such as required in developing clinical data for pre-market clearance of potential therapeutic agents and medical devices which is rarely undertaken in its entirety at Government expense, there

is an identified likelihood that transfer will not occur if the entrepreneur is not afforded some property protection in the innovation offered for development. This likelihood seems even more predictable when considering the extraordinary escalation in the estimated average cost of successfully developing a new drug from one-half million dollars in 1962 to 11.5 million dollars in 1973, or 24.4 million dollars when including the cost of research on projects which did not result in marketed drugs.[1/] When it is recognized that costs to second entrants into the market after patent expiration are a small fraction of the original developer's costs, since the second entrant need not undertake the same R & D risk, it is not difficult to understand industry reluctance to proceed with development of University pharmaceutical inventions without the guarantee of some patent exclusivity.

In this context it is apparent that the existence of a licensable patent right could be a primary factor in the successful transfer of a University innovation to industry and the marketplace, and failure to protect such right may fatally affect a transfer of a major health innovation. There has been

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1/ Scherer, "The Economic Effect of Mandatory Patent Licensing," P. 59, U.S. Energy Research and Development Administration, Public Meeting 1/12/77 and Schwartzman, "Innovation in the Pharmaceutical Industry," pp. 66, 70 and 71.

much speculation that failure to recognize this axiom foreclosed private development of penicillin for over 11 years,[2/] ultimately requiring the Government to undertake all the risks under the pressure of World War II. The Commission endorsed implementation of the Task Force recommendation but only after evaluation of experience under the '71 Statement indicated a need for further policy revisions.

In partial response to the Commission's first recommendation to implement the President's Statement uniformly, the GSA issued a patent section as part of the Federal Procurement Regulations. These regulations include standard contract language to be used by all the agencies when implementing an agency decision to either (1) take title for the agency, (2) leave title with the contractor, or (3) defer determination until the resulting invention is identified. I would emphasize again that these regulations in no way provide any new instructions on when an agency is to use a title, license or deferred patent clause resulting in uniform treatment of contractors dealing with different agencies under similar fact situations.

2/ David Masters, Miracle Drug, The History of Penicillin, published by Gyre & Spotti, Woode, London (1946), pp. 104-105 and

The Law of Chemical, Metallurgical and Pharmaceutical Patents, Forman, Editor, published by Central Book Co., New York (1967).

Prior to issuance of the FPR regulations, the Justice Department raised the question of whether the disposition of future or contingent invention rights to contractors without statutory authority was an unconstitutional disposition of property. This concept was dismissed by the research and development agencies on the basis that even if the possibility of making an invention could be deemed property, the ultimate invention was the property of the inventor under law absent a future assignment to the Government.

Soon after the issuance of these regulations, Public Citizens, joined by 7 Congressmen, again brought suit to enjoin implementation of these regulations on the basis that they provided for contract clauses which permit contractors to retain in some instances the exclusive right to future inventions. The plaintiff, citing Justice as its primary authority, contended that such clauses amount to an unconstitutional disposition of property, as they are not based on statutory authority.

The Justice Department later publicly disavowed that its comments had any support in law, and both cases were dismissed on the basis of plaintiff's failure to show that it was damaged by issuance of the regulations.

Notwithstanding the fact that the Executive prevailed in these cases, the failure of the court to refute the plaintiff's contentions has had serious ramifications. Alleged patent infringers have adopted the Justice Department's initial position as a defense in recent patent infringement cases brought on a patent resulting from Government-supported research. These incidents have led to the belief that the argument that the invention in question was generated in whole or even in part with Government funds may well come to be utilized as a standard defense in patent infringement suits.

While the '71 Statement catalyzed the Court challenges discussed above, the energy crisis of 1973 has catalyzed the Congressional challenge to the '71 Statement.

At the beginning of 1974 the proposed patent clauses attached to the Federal Non Nuclear Energy Research and Development Act of 1974 by the Interior and Insular Affairs Committee provided for Government ownership of all inventions resulting from the proposed research program. Even after a number of attempts by the Executive, industry, and universities to explain the need for a policy which would create an atmosphere encouraging contractor participation in this important program and ultimate utilization of results, the Committee agreed only to insignificant amendments. It was only after industry and

university groups precipitated a fight on the floor of the House which led to the deletion of the initial patent clauses did the Executive gain the bargaining power during Senate-House conference to enable negotiation of the finally enacted energy patent clauses. These clauses, although providing that the Government will normally retain title to resulting inventions, do provide in the Administrator the right to waive title to any invention, either at the time of contracting or upon identification provided he make certain considerations, as well as including specified march-in rights deemed necessary in the public interest.

At the time these clauses were negotiated, the Executive was relatively pleased in being able to redeem the patent policy of a major research and development program from the brink of an inflexible title policy, since the clauses parallel and in some respects are superior to the equivalent provisions of the '71 Statement, especially since they are in legislative form. However, since enactment of the Non-Nuclear Energy Research and Development Act, Congress has routinely attached the ERDA patent provisions to each new research program before it.

This continued Congressional action could eventually result in an ERDA type policy applied to all the agencies. This would merely place in legislative form the same kind of policy

that the Commission's Task Force found wanting, since it requires an agency to utilize its case-by-case discretion in granting a waiver of rights. Current statistics indicate that most agencies are not utilizing this discretion. Examination of agency attitudes appear to evidence the belief that waivers serve the contractor's interest only, and the burden of justifying such waivers should, therefore, be carried entirely by the contractor. If the public interest is to be met, agencies should be evaluating waiver requests and weighing the prospect of agency "advocacy" of the invention against the prospect of contractor "advocacy." Certainly, if a waiver will result in greater effort toward development than will be undertaken by the agency, its denial may well be contrary to the public interest. Yet, most of the major civilian research and development agencies have no identified waiver procedures and no or negligible waiver statistics.

During late 1975 and all through 1976 the Committee on Government Patent Policy met to discuss the dilemma generated by the events discussed above. The Committee agreed that the Congress' apparent abandonment of the President's Statement and the cloud created by the court cases challenging the constitutionality of agency disposition of patent rights were serious matters and have, accordingly, recommended the need

to seek repeal of all existing legislation covering agency disposition of patent rights in favor of Government-wide legislation covering this subject. During its deliberations the Committee considered two approaches within which a uniform Government patent policy might be formulated.

The first of these approaches involved revision of the patent provisions attached to the Federal Non-Nuclear Energy Research and Development Act of 1974, discussed above, to accommodate all the Executive agencies.

The second approach adopted the alternate patent policy proposed by the Commission on Government Procurement's Task Force, also discussed above.

Of the two approaches debated by the Committee, a substantial majority favored the alternate approach, which was deemed to be more likely to maximize utilization of inventive results. This decision resulted in a draft bill which would establish for the first time a uniform Federal policy providing contractor retention of ownership of inventions resulting from Federally-sponsored research, if they have sufficient interest to seek patent protection and declare an intent to commercialize the invention subject to strong march-in rights in the Government. The draft bill repealed, amended, or abolished over 22 existing differing legislative and Presidential Federal patent policies.

Unfortunately, introduction of this bill was overtaken by the Presidential election of 1976, and all clearance procedures ceased in November. However, in a parallel exercise, Congressman Ray Thornton of Arkansas began hearings during 1976 before his Subcommittee on Domestic and International Scientific Planning and Analysis of the Committee on Science and Technology. It seems that the Congressman has arrived at the same conclusion as the Committee on Government Patent Policy, as he introduced on April 6, 1977, H.R. 6249, the "Uniform Federal Research and Development Utilization Act of 1977," which is substantially equivalent to the bill recommended by the Committee.

I understand that Government-funded research is approaching 60 percent of the total research conducted in this country and is still growing as a percentage of the total. It seems clear to me that continuation of a patent policy which permits the agencies to utilize their discretion to determine whether or not the normal incentives of the patent system should be applicable cannot help but to eventually undermine the integrity of our patent system, if substantially all decisions result in Government ownership without further effort toward commercialization.

It is statistically supportable that the delivery of goods to the marketplace in our free society has been dependent on

the private ownership and advocacy of inventive ideas. If our supply of privately owned ideas is reduced due to a larger percentage of the national research budget going into public research and resulting inventions being dedicated to the public without assurance of an advocate, we should question whether our system will be able to continue to compete in the international market with countries who are taking advantage of the world's patent systems.